Nasoalveolar Molding for Infants Born with Clefts of the Lip, Alveolus, and Palate

Barry H. Grayson, D.D.S.[1,2] and Deirdre Maull, D.M.D.[3]

ABSTRACT

Presurgical infant orthopedics has been employed since the 1950s as an adjunctive neonatal therapy for the correction of cleft lip and palate. Nasoalveolar molding represents a paradigm shift from the traditional methods of presurgical infant orthopedics. One of the problems that the traditional approach failed to address was the deformity of the nasal cartilages in unilateral, as well as bilateral, clefts of the lip and palate and the deficiency of columella tissue in infants with bilateral clefts.

The Nasoalveolar Molding (NAM) technique utilizes wire and acrylic nasal stents attached to an intraoral denture. This appliance is used to mold the nasal cartilages, premaxilla, and alveolar ridges into normal form and position during the neonatal period. In effect, this presurgical management of the cleft infant is intended to reduce severity of the oronasal deformity prior to surgery.

This technique takes advantage of the malleability of immature nasal cartilage and its ability to maintain a permanent correction of its form. In addition, we demonstrate the ability to nonsurgically elongate the columella in bilateral cleft lip and palate through the application of tissue expansion principles. This is performed by gradual elongation of the nasal stents and the application of forces that are applied to the lip and nose. Utilization of the NAM technique has eliminated surgical scars associated with traditional columella reconstruction, has reduced the number and cost of revision surgical procedures, and has become the standard of care in this Cleft Palate Center.

KEYWORDS: Nasoalveolar molding, NAM, unilateral cleft lip and palate, bilateral cleft lip and palate

Cleft lip and palate can arise with considerable variation in severity and form. Generally, the wider, more extensive clefts are associated with more significant nasolabial deformity. These clefts, deficient in hard and soft tissue elements, present a significant surgical challenge to achieve a functional and cosmetic outcome. Even a mild incomplete unilateral cleft lip in the absence of a cleft palate can be associated with a nasal deformity. Most surgeons would agree that their chance of achieving a finer surgical scar, good nasal tip projection, and more symmetrical and precisely defined nasolabial complex would be better in an infant who presents with a minor cleft deformity. A finer scar forms when a surgical incision heals under less rather than more tension. The principal objective of presurgical nasoalveolar molding (NAM) is to reduce the severity of the initial cleft deformity. This enables the surgeon and the patient to enjoy the benefits associated with repair of cleft deformity that is of minimal severity.

Cleft Lip Repair: Trends and Techniques; Editor in Chief, Saleh M. Shenaq, M.D.; Guest Editor, Joseph K. Williams, M.D., F.A.C.S., F.A.A.P.; *Seminars in Plastic Surgery*, Volume 19, Number 4, 2005. Address for correspondence and reprint requests: Barry H. Grayson, D.D.S., Institute of Reconstructive Plastic Surgery, New York University Medical Center, 560 First Avenue, New York, NY 10016. [1]Institute of Reconstructive Plastic Surgery, New York University Medical Center, [2]New York University College of Dentistry, New York, New York; [3]Craniofacial Program, Inova Fairfax Hospital for Children, Falls Church, Virginia. 1535-2188,p;2005,19,04,294,301,ftx,en;sps00181x.

The unilateral cleft deformity is characterized by a wide nostril base and separated lip segments on the cleft side. The affected lower lateral nasal cartilage is displaced laterally and inferiorly, which results in a depressed dome, the appearance of an increased alar rim, an oblique columella, and an overhanging nostril apex. If there is a cleft of the palate, the nasal septum deviates to the noncleft side with an associated shift of the nasal base.[1]

The bilateral cleft lip deformity typically arises with a procumbent or rotated premaxilla. The alar base width is significantly increased, and the lip segments are widely separated.[2] The flattened nasal tip is tethered directly to the prolabium by a severely deficient or absent columella. The lower lateral alar cartilages are flared and concave where they should be convex. The greatest challenge for esthetic reconstruction is the absent or deficient columella.

HISTORY

Numerous techniques have been documented over the centuries to improve the position of the cleft alveolar segments. In 1686, Hoffman described the use of a head cap with arms extended to the face to retract the premaxilla and narrow the cleft. There have been many improvements in this method of using the head as extraoral anchorage,[3] and it is used today to retract the premaxilla.[4] The concept of an intraoral device to reposition the cleft alveolar segments is attributed to McNeil.[5] Through a series of acrylic plates, the segments are actively molded into the desired position. In 1975, Georgiade and Latham[6] introduced a pin-retained appliance to simultaneously retract the premaxilla and expand the posterior segments over a period of days. In response to controversy associated with active retraction of the premaxilla, Hotz et al[7] described the use of a passive orthopedic plate to align the cleft segments slowly. The premaxilla is not retracted, Hotz et al felt that by age 10 the face has grown forward into appropriate balance with the premaxilla. All of these appliances were designed to correct the alveolar cleft only, despite the fact that the cleft nasal deformity remains the greatest esthetic challenge.

In 1993, Grayson et al[8] described a technique to correct the alveolus, lip, and nose in infants born with cleft lip and palate. The original research for molding cartilage was performed by Matsuo et al.[9–12] Matsuo recognized that the cartilage in the newborn is soft and lacks elasticity. He believed that the high level of estrogen at the time of birth correlates with the increased hyaluronic acid, which inhibits the linking of the cartilage intercellular matrix. This process may be necessary to relax ligaments, cartilage, and connective tissue, enabling the fetus to pass through the birth canal. The level of estrogen begins to decline immediately after birth. Matsuo used a stent in the form of a pair of silicone tubes to shape the nostrils, with some limitations. These include the need for an intact nasal floor (Simonart's band or lip adhesion) and the inability to direct the force because the stent expands circumferentially. Grayson et al adapted his nasal stent to extend from the anterior flange of an intraoral molding plate.[13–15] The greatest advantage of NAM is that it enables the practitioner to apply force skillfully to shape the nasal cartilage. Because the stent is extended from a molding plate, an intact nasal floor is not required.

OBJECTIVES

The principal objective of presurgical NAM is to reduce the severity of the initial cleft deformity. This enables the surgeon to enjoy the benefits associated with repair of an infant who presents with a minimal cleft deformity. These goals include lip segments that are almost in contact at rest, symmetrical lower lateral alar cartilages, and adequate nasal mucosal lining, which permits postsurgical retention of the projected nasal tip (Fig. 1A).

Additional objectives of NAM include reduction in the width of the alveolar cleft segments until passive contact of the gingival tissues is achieved. As reduction of the alveolar gap width is accomplished, the base of the nose and lip segments achieve improved alignment. Tapes that actively bring the lip segments together are used in conjunction with the molding plate and nasal stent. Taping the lips together helps to make the inclined columella upright along the midsagittal plane. As the lower midface skeletal elements (alveolar ridges and lower maxilla) improve in relation to each other, the overlying soft tissues follow (Fig. 1B–D).

As reduction of the alveolar gap width is accomplished, the base of the nose and lip segments achieve improved alignment. As the alveolar ridges and lower maxilla improve in relation to each other, the overlying soft tissues improve. The alar rim, which was initially stretched over a wide alveolar cleft deformity, shows some laxity, which enables it to be elevated into a symmetrical and convex form. The nasal tip on the cleft side is overcorrected in its forward projection. This is achieved through the use of a nasal stent, an intraoral molding plate, and surgical tape (Fig. 2). In the infant with bilateral clefts of the lip alveolus and palate, the objective of presurgical NAM includes the nonsurgical elongation of the columella, centering of the premaxilla along the midsagittal plane, and retraction of the premaxilla in a slow and gentle process to achieve continuity with the posterior alveolar cleft segments. Additional objectives include a reduction in the width of the nasal tip, improved nasal tip projection, and a decrease in the nasal alar base width.

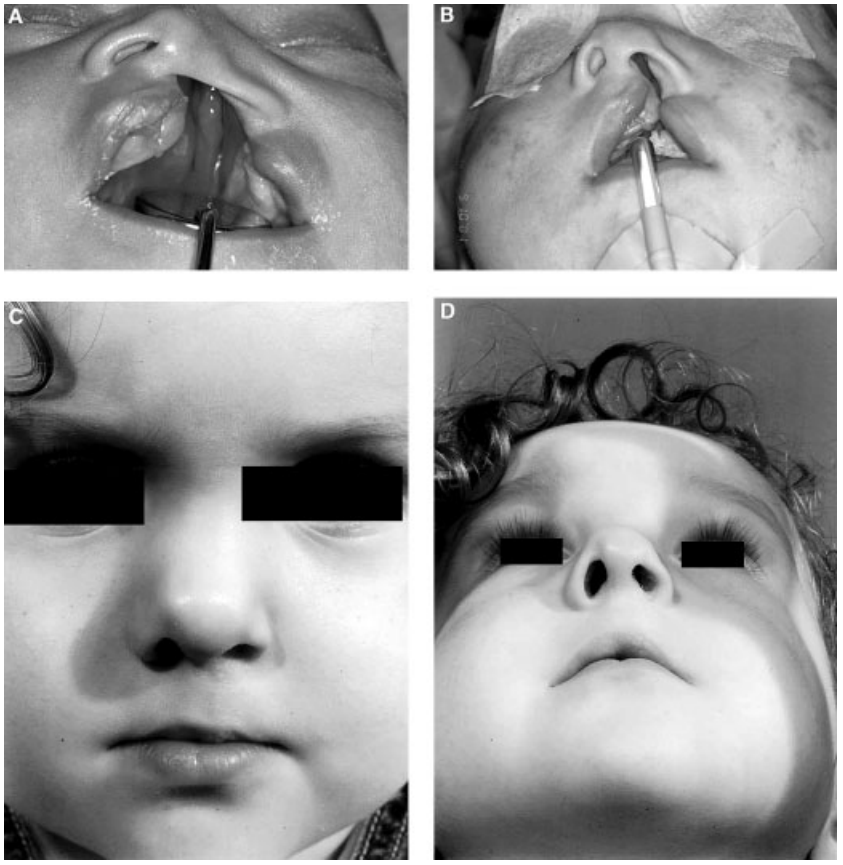

Figure 1 (A) Patient before implementation of nasoalveolar molding. Note the wide nostril base and widely separated lip segments. The affected lower lateral alar cartilage is displaced laterally and inferiorly, which results in a depressed dome, the appearance of an increased alar rim, and an overhanging nostril apex. (B) Patient after nasoalveolar molding and just before primary surgical repair. Note the marked reduction in severity of cleft deformity, which improves the prognosis. The lip segments are in close approximation at rest; note the uprighting of the columella, the convexity of the lower lateral alar cartilage, and the projection of the nasal tip. (C) Frontal view and (D) base view of a patient at 2 years, 5 months of age showing a minimally detectable lip scar and good nasolabial esthetics.

PROCEDURE

A heavy-bodied silicone impression material is used to take the initial impression as soon after birth as possible, when the cartilage is plastic and moldable. In case of an airway emergency, the surgeon is always present to help with the impression. The infant is held upside down by the surgeon, and the impression tray is inserted into the oral cavity. The tray is seated until impression material is observed just beginning to extrude past its posterior border. The infant is kept in the inverted position to keep the tongue forward and to allow fluids to drain out of the oral cavity. Once the impression material is set, the tray is removed, and the mouth is examined for residual impression material that may be left behind. A cast or model of the alveolar anatomy is made by filling the impression with a dense plaster material (dental stone). The molding plate is fabricated on the dental stone model. It is made of hard clear acrylic and is lined with a thin layer of soft denture material. Care is taken to reduce the border of the plate in the area of the labial frenum attachments and other areas that may be likely to ulcerate. Parents are instructed to keep the plate in full time and to take it out for cleaning as needed, at least once a day. Initially, it may take longer to feed the infant with the plate in place, but the child quickly adjusts and parents report that the infant soon will not eat without it (Fig. 3). The appliance is secured extraorally to the

Figure 2 Unilateral nasal stent in position showing lip taping and correction of nasal form.

Figure 3 Infant feeding with bilateral molding plate in place.

cheeks and bilaterally by surgical tapes, which have an orthodontic elastic band at one end. The elastics loop over a retention arm extending from the anterior flange of the plate (Fig. 4A, B). The retention arm is positioned approximately 40 degrees down from the horizontal to achieve proper activation and to prevent unseating of the appliance from the palate. The tapes are changed once a day.

Weekly visits are required to modify the molding plate to guide the alveolar cleft segments into the desired position. Closure of the alveolar gap brings the lip segments together, reduces the nasal base width, and introduces laxity of the alar rim. Care should be taken not to add the nasal stent before achieving laxity of the alar rim because an increase of the nostril circumference may result.

In the unilateral cleft, only one retention arm is used. To determine its location on the labial border of the molding plate, the cleft lip segments are pulled together while centering the philtrum and columella. A pencil mark is placed at the junction of the cleft lip segments, and the retention arm is attached at this point. The vertical position of the retention arm should be at the junction of upper and lower lips at rest. This allows approximation of the cleft lip segments and does not interfere with the resting position of the lower lip.

When the retention arms are engaged by the tape-elastic system, the elastics (inner diameter 0.25 inch, wall thickness heavy) should be stretched approximately two times the resting diameter for proper activation force (2 oz). The amount of force may vary depending on the clinical objective and the mucosal tolerance of pressure. Retraction of the premaxilla requires greater elastic traction force than is required for closure of a unilateral alveolar gap.

At the third visit, the parents are instructed to place tapes to approximate the cleft lip segments. The tape should be applied at the base of the nose (nasolabial angle) and not low on the lip near the vermilion border. Taping too low can cause undesirable horizontal lengthening of the lip over time. The tape should be applied to the noncleft side first, then pulled over and adhered to the cleft side; the philtrum and columella should be brought to the midline. Lip taping provides some of the benefits of a surgical lip adhesion without the associated surgical morbidity, cost, and scarring.

When the cleft alveolus is reduced to 5 mm or less, the nasal stent is added. The stent is made of 0.036-gauge round stainless steel wire and takes the shape of a swan neck (Fig. 5). A template for the nasal stent is made from a malleable rope of soft dental wax. The wax rope is attached to the labial flange of the molding plate, near the base of the retention arm. It extends forward and then curves backward (in the form

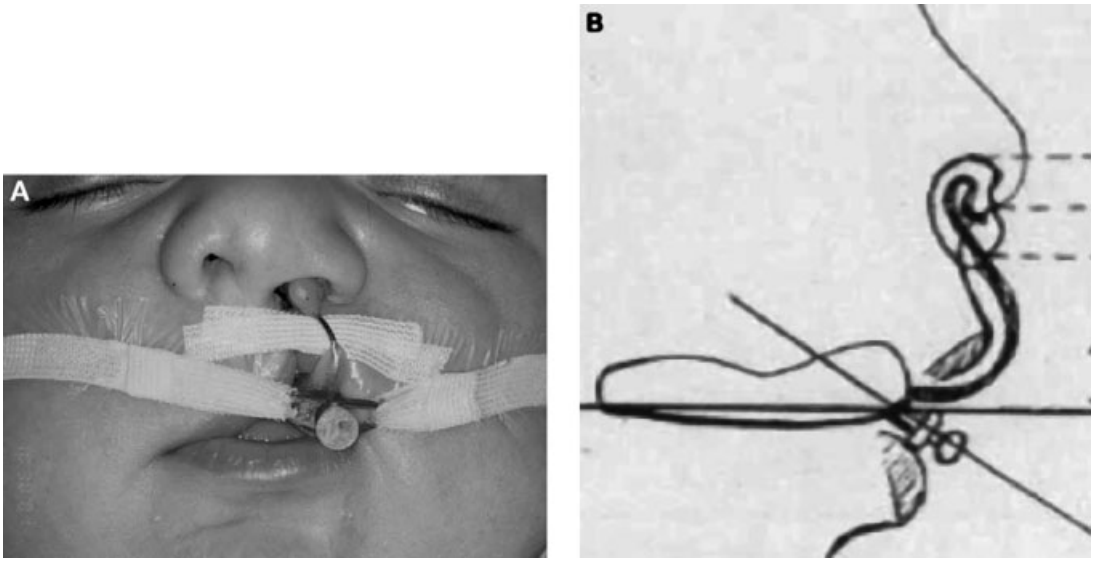

Figure 4 (A) Unilateral nasal stent in position showing lip taping. (B) The retention arm is positioned ~40 degrees down from the horizontal to achieve proper activation and to prevent unseating of the appliance from the palate.

Figure 5 Nasal stent added to the intraoral molding plate.

of a swan neck), entering 3 to 4 mm past the nostril aperture. By copying the shape of this wax template, one can easily form the wire armature of the nasal stent. As the wire extends into the nostril, it is curved back on itself to create a small loop for retention of the intranasal portion of the nasal stent. This hard acrylic component is shaped into a bilobed form that resembles a kidney. A layer of soft denture liner is added to the hard acrylic for comfort. The upper lobe enters the nose and gently lifts the dome until a moderate amount of tissue blanching is evident. The lower lobe of the nasal stent lifts the nostril apex and defines the top of the columella (Fig. 6).

In the patient with bilateral clefts, there is a need for two retention arms and nasal stents. The fabrication steps are the same as described for the unilateral cleft. Each nasal stent originates from the molding plate at the base of a retention arm. After the nasal stents are added, attention is focused on nonsurgical lengthening of the columella. To achieve this objective, a horizontal band of soft denture material is added to join the left and right lower lobes of the nasal stents, spanning the base of the columella. This band sits at the nasolabial junction and defines this angle as the nasal tip continues to be lifted and projected forward. Tape is adhered to the prolabium underneath the horizontal lip tape and stretches downward to engage the retention arms with elastics. This vertical pull is a counterstretch to the upward force applied to the nasal tip by the nasal stent. Taping downward on the prolabium helps to lengthen the columella and vertically lengthens the often small prolabium. The horizontal lip tape is added after the vertical prolabial tape is in place (Fig. 7).

Primary surgical closure of the lip and nose is performed from 3 to 5 months of age.[16–19] Because the

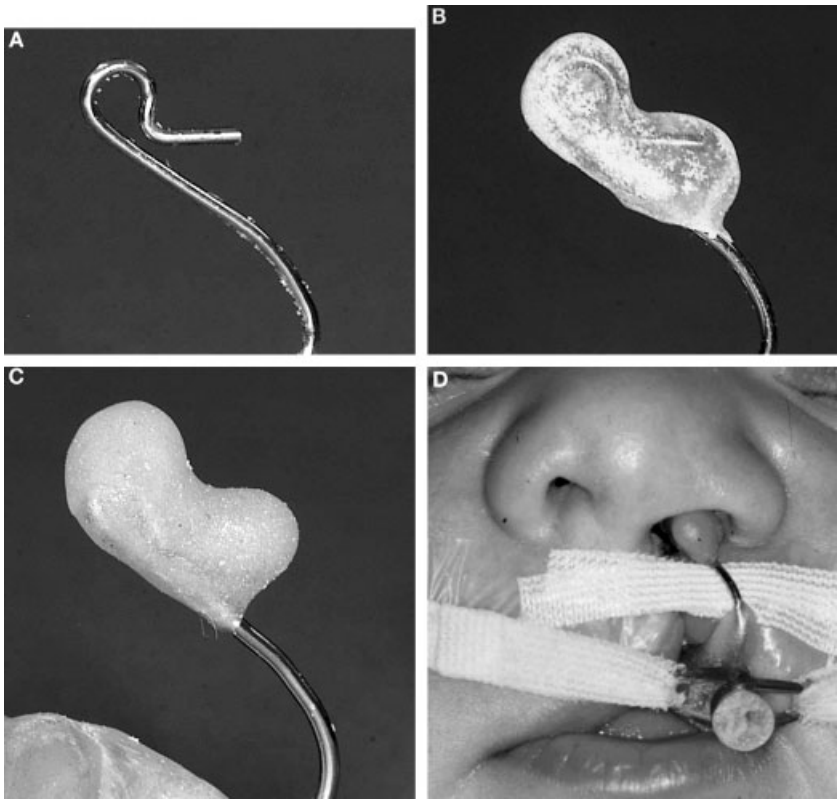

Figure 6 (A) As the wire armature of the nasal stent extends into the nostril, it is curved back on itself to create a small loop for retention of the intranasal portion of the nasal stent. (B) Hard acrylic (methylmethacrylate) is applied to the wire armature and shaped into a bilobed form that resembles a kidney. (C) The hard acrylic nasal stent is coated with a thin layer of soft denture liner for comfort. (D) The upper lobe of the nasal stent enters the nose and gently lifts the dome until a moderate amount of tissue blanching is evident. The lower lobe of the nasal stent lifts the nostril apex and defines the top of the columella.

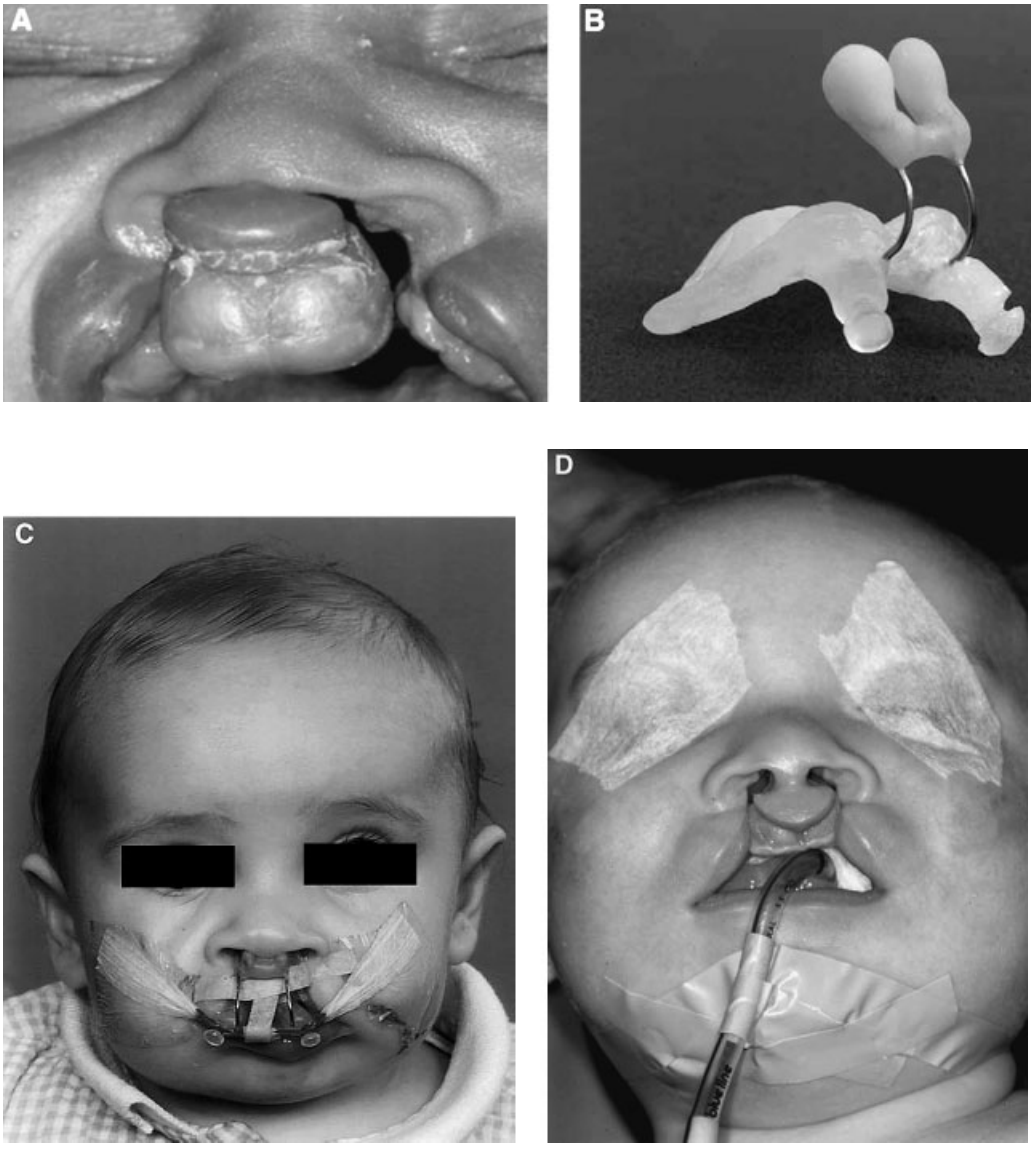

Figure 7 (A) Bilateral complete cleft with nearly absent columella, wide nasal tip, everted premaxilla, and widely separated lip segments. (B) The bilateral nasoalveolar molding plate appliance. Note the horizontal band of soft denture material that joins the left and right lower lobes of the nasal stents. This prolabial band'' spans the columella, pressing in on the nasolabial fold and up at the nostril apices. (C) The bilateral nasoalveolar molding plate in place. Tape is adhered to the prolabium, underneath the horizontal lip tape, and stretches downward to engage the retention arms with elastics. Additional tapes are used to support the appliance upward and against the premaxilla and posterior alveolar segments. (D) After 4 months of NAM therapy and before the primary surgical repair. Note the development of columella. The premaxilla has been gently retracted into the oral cavity, and the lip segments are in close approximation at rest. The nasal mucosal lining has been stretched by the nasal stents to reduce postsurgical pull-down of the projecting nasal tip (not shown). (E) Patient at 1 year, 6 months of age.

alveolar segments are in approximation, a gingivoperiosteoplasty (GPP) is simple for the surgeon to perform, avoiding extensive dissection[20,21] and not affecting growth of the midface.[22,23] The surgical technique for primary cleft lip and nose repair must be modified in a way that takes advantage of the NAM preparation.[19]

COMPLICATIONS

There are few serious complications associated with NAM. The most common is irritation of the oral mucosal or gingival tissue. Intraoral tissues may ulcerate from pressure or rubbing. Common areas of breakdown are the frenum attachments, the anterior premaxilla, and the posterior fauces as the molding plate is retracted. The infant should be checked at each visit, and the molding plate should be properly relieved in all areas that are exerting excessive pressure. The intranasal lining of the nasal tip can become inflamed if too much force is applied by the upper lobe of the nasal stent. Notching along the alar rim can occur if the lower lobe is not positioned or shaped correctly. The area under the horizontal prolabium band can become ulcerated if the band is too tight.

The most common area of soft tissue irritation is the cheeks. The tapes should be removed slowly and carefully to avoid skin irritation. Tape removal solvents or warm water can facilitate the removal of tapes. If the tissue remains irritated, a skin barrier such as DuoDerm or Tegaderm can be used as a base on which the tape-elastic retraction system can be attached. It is sometimes recommended that aloe vera gel be applied to the cheeks when changing tapes. Poor compliance by the parents can cause loss of valuable treatment time.

There is a risk that the molding plate will become dislodged and obstruct the airway. Taping the arms too horizontally or with inadequate activation increases the possibility that the posterior border of the molding plate will drop down onto the tongue. There is only one reported instance in which this happened, causing a temporary airway obstruction. We place a 5-mm-diameter hole in the center of the molding plate at fabrication to provide for passage of air in the event that the molding plate drops down from the rear and causes obstruction. The hole, centrally located on the palatal portion of the molding plate, will in most instances allow adequate airflow.

BENEFITS

The benefits of NAM are numerous. In the short term, the tissues are well aligned before primary lip and nose repair, which enables the surgeon to achieve a better and more predictable outcome with less scar tissue formation. In the long term, studies indicate that the change in nasal shape is stable[24] with less scar tissue and better lip and nasal form. This improvement reduces the number of surgical revisions for excessive scar tissue, oronasal fistulas, and nasal and labial deformities.[25] With the alveolar segments in a better position and increased bone bridges across the cleft, the adult teeth have a better chance of erupting in a good position with adequate periodontal support.[26]

Santiago et al[21] found that 60% of patients who underwent NAM and GPP did not require secondary bone grafting. Sato et al[26] found that, in the remaining 40% who did need a bone graft, there was more bone remaining in the graft site than in patients who did not previously undergo GPP. This was explained by the presence of bone bridges in the graft site resulting from the primary GPP. Henkel and Gundlach[27] found that, in 68% to 73% of patients in whom a Millard-type GPP was performed, a secondary bone graft was not required. Fewer surgeries result in substantial cost savings for families and insurance companies.[28] Another important benefit of NAM is the opportunity for the

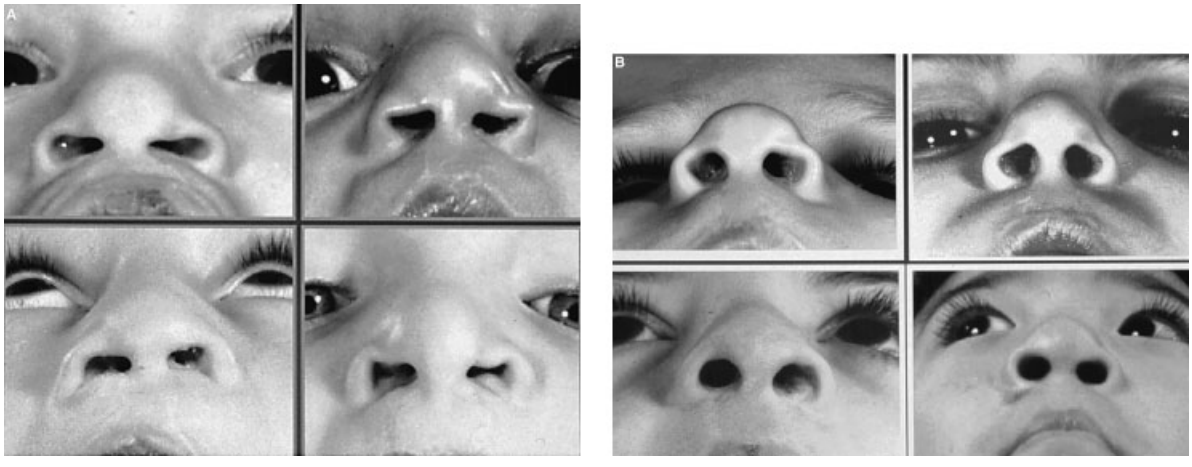

Figure 8 (A) Before the initiation of NAM and the associated surgical technique, there were scars at the base of the columella and depressed and broad nasal tips with compromised nasal esthetics. (B) Since the introduction of NAM and presurgical columella elongation, there has been reduced scarring of the lip-nose complex and improved nasal tip projection and nasolabial esthetics.

parents to take part actively in the habilitation of their child.

NAM has evolved over the past decade into its present form through contributions made by practicing clinicians and parents. This method of treatment requires attention to detail with appliance adjustments that are at times less than a millimeter in dimension.

Clinical skills in NAM develop over time. Efficiency in treating patients increases as these clinical skills improve, and these skills may be advanced by the training of a dental assistant or laboratory technician to make adjustments to the molding plate under direct supervision of the practicing clinician. Since the initiation of NAM and the associated surgical technique, there has been a significant difference in the outcome of primary surgical cleft repair (Fig. 8).

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